UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,412	08/28/2003	Nicholas Thomas	HO-P02190US1	6563

26271 7590 05/17/2006

FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER	
BEISNER, WILLIAM H	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,412	THOMAS ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/05; 2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 10/28/05 and 2/28/06 have been considered and made of record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 22-25 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Mian et al.(US 6,319,469) and Cathey et al.(US 5,660,993).

The reference of Sheppard, Jr. et al. discloses an assay device and method of use which includes a disk device that includes a plurality of micro-channel elements (shown in Figure 2). Each element includes a cell growth chamber (24) which allows cells to be introduced and cultured for attachment (See column 4, lines 14-17). The reference discloses detection of test compounds on the cultured cells (See column 7, lines 13-32 and Example 3).

Claim 22 first differs by reciting specific construction limitations such as the use of multiple micro-channel elements and cover limitations.

The reference of Sheppard, Jr. et al. discloses that the device as disclosed by Mian et al. can be used to construct the system of Sheppard, Jr. et al. (See column 3, lines 28-38 which makes reference to Application 08/768,990 in the specification of Sheppard, Jr. et al.).

The reference of Mian et al. discloses a base and cover construction for forming a plurality of micro-channel elements (See Figure 1B).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the construction techniques of Mian et al. to construct the device of Sheppard, Jr. et al. for the known and expected result of providing a device as is required of the Sheppard, Jr. et al. reference.

Claim 22 further differs by reciting that the device includes "a hydrophobic barrier or valve in at least one of said chambers or said channels" "wherein said valve comprises a localized region of hydrophobicity within said chamber or said channel".

The references of Sheppard, Jr. et al. and Mian et al. disclose that the use of valves to control the flow of liquid between the chambers of the device is known (See column 13, lines 1-9; column 13, line 65, to column 14, line 30; and column 20, lines 12-67, of the reference of Sheppard, Jr. et al.). The list of disclosed valves includes capillary microvalves wherein the fluid flow is stopped based on the geometry of the channel and surface properties of the substrate material and fluid.

The reference of Cathey et al. discloses that it is known in the art to control the flow of liquids between the chambers or channels of a capillary flow device by using capillary valves or "hydrophobic areas in that particular region" in which one wishes to slow or impede fluid flow through a particular region of the channel (See column 5, lines 47-60). The reference of Cathey et al. establishes that a capillary valve and localized region of hydrophobicity are art recognized equivalents for enhancing or controlling the flow of fluids through an assay device.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a hydrophobic region or localized region of hydrophobicity within the device of the device of the reference of Sheppard, Jr. et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, control the flow of fluid between the chambers as is suggested and required of the reference of Sheppard, Jr. et al.

With respect to claims 23 and 24, the reference of Sheppard, Jr. et al. discloses that the device is intended to be used with a suspension of cells that are to be attached in the cell chambers (See column 4, lines 1-17).

With respect to claim 25, the device suggested by the combination of the references of Sheppard, Jr. et al. and Mian et al. would be a rotatable disc with a center inlet port and annular sample chamber.

With respect to claim 33, the reference of Sheppard, Jr. et al. discloses the use of three-dimensional surfaces for the cell accumulation chamber (See column 16, lines 38-42). With respect to the use of beads or pillars for cell attachment, the use of surface area extending surfaces in cell culture is well known in the art for the known and expected result of increasing the surface area of attachment for the cells to attach and thus increasing the number of cells which can be maintained within the cell culture chamber (24).

With respect to the use of inlet channels of one size verses an outlet of a smaller size of claims 34 and 35, the reference of Mian et al. discloses that it is known in the art to control the flow of liquid through a plurality of zones using changes in cross-sectional area between the zones (See column 19, lines 25-63).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide differences in cross-section between the inlet and outlet of the culture chamber and other chamber for the known and expected result of controlling the flow of liquid between the difference chambers.

With respect to claims 36-38, the claims differ by reciting the use of additional detection chambers for detecting metabolites released by the cell culture.

While the reference of Sheppard, Jr. et al. discusses the detection of cell metabolites, the reference does not detect them in a separate chamber. However, based on the plurality of different detection schemes disclosed by both the reference of Sheppard, Jr. et al. and the reference of Mian et al. (See the Examples of both references), it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide additional detection chamber separate from the culture chamber for the known and expected result of providing an alternative means recognized in the art to achieve the same result, detection of metabolites produced by the cultured cells in response to treatment agents exposed to the cells.

6. Claims 21, 26 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Mian et al.(US 6,319,469) and Cathey et al.(US 5,660,993) taken further in view of Chen et al.(US 5,800,778).

The combination of the references of Sheppard, Jr. et al., Mian et al. and Cathey et al. has been discussed above.

Claims 21 and 26 further differ by reciting that one or more components (the cover) of the device are constructed of a gas permeable plastic material.

The reference of Chen et al. discloses that it is known in the art to employ a gas permeable cover in a test device which is constructed with a base including channels and chambers with the gas permeable cover. The reference discloses that the use of the cover provides increased growth rates from an enhanced oxygen environment (See column 3, lines 6-7).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of the primary reference with a gas permeable cover member for the known and expected advantages disclosed by the reference of Chen et al.

With respect to the cell attachment means of claim 21, the reference of Sheppard, Jr. et al. discloses the use of non-specific cell adhesion coating (See column 4, lines 1-17).

With respect to the specifics of the cell attachment means of claims 29-31, the reference of Sheppard, Jr. et al. discloses the use of chemical surface treatments or the use of adhesion proteins (See column 16, lines 1-37). The specific adhesion protein employed would have been well within the purview of one having ordinary skill in the art using well known proteins such as collagen or fibronectin.

With respect to claim 32, the reference of Sheppard, Jr. et al. discloses the use of three-dimensional surfaces for the cell accumulation chamber (See column 16, lines 38-42). With respect to the use of beads or pillars for cell attachment, the use of surface area extending surfaces in cell culture is well known in the art for the known and expected result of increasing the surface area of attachment for the cells to attach and thus increasing the number of cells which can be maintained within the cell culture chamber (24).

7. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Mian et al.(US 6,19,469); Cathey et al.(US 5,660,993) and Chen et al.(US 5,800,778) taken further in view of Wolfe et al.(US 5,190,879).

The combination of the references of Sheppard, Jr. et al., Mian et al., Cathey et al. and Chen et al. has been discussed above.

While the reference suggest the use of a gas permeable cover, the above claims recite specific materials for the gas permeable material.

The reference of Wolfe et al. provides a list known materials which can be used as a gas permeable material in a culture device (See column 2, lines 39-68).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any of the known gas permeable materials as the cover member for the known and expected result of providing an alternative means recognized in the art to achieve the same result, provide gas exchange to a culture chamber.

8. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Mian et al.(US 6,319,469) and Cathey et al.(US 5,660,993) taken further in view of Cook (WO 94.26413).

The combination of the references of Sheppard, Jr. et al., Mian et al. and Cathey et al. has been discussed above.

While the reference of Sheppard, Jr. et al. discloses the use of optically detectable labels within the chambers (See column 3, lines 39-67), Claims 39 and 40 differ by reciting that the device includes a layer of a scintillant substance and includes a binding moiety.

The reference of Cook discloses that it is conventional in the art to study of the interaction of biological molecules with cultured cells using a layer of a scintillant substance and a binding moiety (See pages 9-17).

In view of this teaching, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ the scintillation assay technique disclosed by the reference of Cook in the system of the modified primary reference of Sheppard, Jr. et al. for the known and expected result of providing an art recognized means for observing cellular processes with respect to a reagent as is performed in the system of the modified primary reference.

Response to Arguments

9. With respect to the rejection of Claims 22-25 and 33-38 under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Mian et al.(US 6,319,469) and Cathey et al.(US 5,660,993), Applicants argue (See pages 2-4 of the response dated 2/28/2006) that the rejection is improper because the hydrophobic and hydrophilic areas in the device of Cathey do not provide a capillary valve function but rather function to impede or enhance flow and having nothing to do with stopping/starting flow as in a capillary valve. Applicants stress that the Examiner has erroneously concluded that the hydrophobic and hydrophilic regions of Cathey function as capillary stop/flow valves because they are discussed in the same paragraph. As a result of the Examiner's alleged error, Applicants conclude that the 35 USC 103 rejection of record is improper because the capillary valve of Mian's and Sheppard's device are not functional equivalents to the hydrophobic and hydrophilic regions of Cathey.

In response, Applicants' comments are not found to be persuasive for the following reasons. First, the Examiner maintains that one of ordinary skill in the art in view of the disclosure of Cathey et al. (column 5, lines 47-60) would recognize the hydrophobic regions to be a functional equivalent to a capillary valve. One of ordinary skill in the art would recognize that a hydrophobic material positioned within a capillary channel of the device of Cathey et al. would impede or stop the flow of liquid within the channel based merely on the driving pressures applied to the sample liquid. As with the capillary valve, above a certain driving pressure there is flow and below there is no flow. It is not clear how Applicants can conclude that the hydrophobic regions of Cathey et al. are used merely for controlling flow direction and do not stop the flow of liquid sample through the device, especially when stopping the flow not the direction of flow is a desired effect in the disclosure of the reference of Cathey et al. (See column 3, lines 50-52). Note controlling the flow direction of the liquid sample would require the use of both hydrophilic and hydrophobic regions. Also, the Examiner is unable to find a reference to controlling the direction of flow in the paragraph that Applicants stress that the Examiner has erroneously interpreted.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

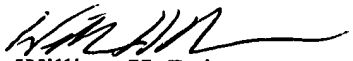
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB